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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/017,549 | 12/14/2001 | Richard Charles Turek | CL/V-31679A | 8133 |

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THOMAS HOXIE
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

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| EXAMINER |
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PENG, KUO LIANG

| ART UNIT | PAPER NUMBER |
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1712

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|--------------|----|
| Office Action Summary | Application No. | Applicant(s) | PL |
| | 10/017,549 | TUREK ET AL. | |
| | Examiner | Art Unit | |
| | Kuo-Liang Peng | 1712 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12/14/01 Filing .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 9-22 is/are allowed.

6) Claim(s) 1-8,23-25,27,29 and 30 is/are rejected.

7) Claim(s) 26 and 28 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. The followings are Examiner's questions/suggestions:
 - In Claim 2 (line 2), should "a" be -- an --?
 - In Claim 5, should "fluorine-containing monomer, hydrophilic monomer, hydrophobic monomer, or a copolymer thereof" be -- a polymer or a copolymer derived from fluorine-containing monomer, hydrophilic monomer or hydrophobic monomer --?
 - In Claim 5 (lines 3-4), Claims 6 and 15 (line 2), Claim 12 (line 3) and Claims 20 and 27 (line 4), should "a mixture" be -- mixtures --?
 - In Claim 20 (line 3) and Claim 27 (line 4), should "and" be -- , --?
 - In Claims 20 and 27 (line 4), should "or" be -- and --?

Specification

2. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any text.
3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-6, 24-25, 27 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Molock (US 5,292,350).

With respect to Claim 1, Molock discloses a soft, hydrogel contact lens which has a dye dispersed substantially uniformly throughout the lens (col. 2, lines 59-61). Example 1 exemplifies a contact lens wherein the dye is incorporated into a polymer matrix. It is noted that Molock's dye reads on the pigment of the instant claim because a pigment is defined as "any substance that imparts color to another material or mixture" (Applicants' specification, page 6, last paragraph). Molock's contact lens prepared in Example 1 has an oxygen permeability of $29 \times 10^{-11} \text{ cm}^2 \cdot \text{ml O}_2/\text{sec} \cdot \text{ml. mm Hg}$ (Table 1 and col. 6, lines 13-15). It is noted that there is a typographical error in the unit of the oxygen permeability recited in Molock's specification (col. 6, lines 13-15), which should be $\text{cm}^2 \cdot \text{ml O}_2/\text{sec} \cdot \text{ml. mm Hg}$ (i.e., $(\text{cm}^3 \text{ oxygen})(\text{cm}^2)/(\text{ml})(\text{sec})(\text{mmHg})$), rather than $\text{cm} \cdot \text{ml O}_2/\text{sec} \cdot \text{ml. mm Hg}$. Applicants' specification indicates that the oxygen transmissibility is preferably at least 60 barrers/mm ($[(\text{cm}^3 \text{ oxygen})(\text{mm}) /(\text{cm}^2)(\text{sec})(\text{mmHg}) \times 10^{-9}] / \text{mm}$) and the lens center thickness is typically more than about 30 microns (i.e., 0.030 mm) (page 9, 2nd paragraph). In other words, Applicants' specification indicates that the oxygen permeability is preferably at least $60 \times 10^{-9} \text{ ((cm}^3 \text{ oxygen})(\text{mm}) /(\text{cm}^2)(\text{sec})(\text{mmHg})] / \text{mm}$ $\times 0.030 \text{ mm} = 1.8 \times 10^{-9} \text{ (cm}^3 \text{ oxygen})(\text{mm})$

$/(cm^2)(sec)(mmHg) = 1.8 \times 10^{-10} (cm^3 \text{ oxygen})(cm^2)/(ml)(sec)(mmHg) = 18 \times 10^{-11} (cm^3 \text{ oxygen})(cm^2)/(ml)(sec)(mmHg)$ because the oxygen transmissibility is obtained by dividing the oxygen permeability by the average thickness of the lens (specification, page 12, last two lines).

As such, Molock's contact lens does possess a high oxygen permeability because the oxygen permeability (i.e., $29 \times 10^{-11} \text{ cm}^2 \cdot \text{ml O}_2/\text{sec} \cdot \text{ml. mm Hg}$) of Molock's contact lens is even higher than the least value of Applicants' preferable oxygen permeability (i.e., $18 \times 10^{-11} (cm^3 \text{ oxygen})(cm^2)/(ml)(sec)(mmHg)$).

With respect to Claim 2, Molock further teaches that the contact lens is intended to be used for the eyes (col. 4, lines 8-14). In other words, the surface of the Molock's contact lens is in contact with an ophthalmic environment. Furthermore, it is noted that the majority of the monomers used in Example 1 are hydrophilic monomers such as HEMA and MAA (col. 4, lines 35-59). Therefore, Molock's contact lens surface is also hydrophilic. As such, Molock's contact lens is surrounded by an ophthalmically compatible surface. It is further noted that the instant claim does not exclude the possibility of an ophthalmic molding wherein the compositions of the bulk portion and the surface portion are the same.

With respect to Claim 5, the polymer matrix of the contact lens is a copolymer of a hydrophilic monomer (col. 4, lines 45-59).

With respect to Claim 6, the dye, which reads on Applicants' pigment, is organic (col. 3, lines 48-68).

With respect to Claim 24, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i). As such, although Molock does not use a pigment dispersion which is prepared as a separate component from the

“crosslinkable or polymerizable material”, Molock’s contact lens reads on the soft, tinted ophthalmic lens of the instant claim because the dispersing agent which is crosslinkable or polymerizable with component (i) in the instant claim is eventually incorporated into the final lens matrix (i.e., absence of the pigment dispersion) after polymerization or crosslinking.

With respect to Claim 25, the rejection for Claim 24 applies.

With respect to Claim 27, the dye is dispersed in a monomer mixture comprising HEMA (Example 1).

With respect to Claims 29-30, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i) (i.e., using component (i) as the dispersing agent). As such, although Molock does not use a pigment dispersion which is prepared as a separate component from the “crosslinkable or polymerizable material”, Molock’s composition reads on the composition of the instant claim because the “pigment dispersion” is essentially the final “composition” in the instant claims.

6. Claims 1-3, 5-8, 24-25, 27 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley (US 4,252,421) as evidenced by Muller (US 4,486,577).

With respect to Claim 1, Foley discloses a hydrogel (i.e., soft) contact lens having a tinted core prepared by crosslinking 2-hydroxyethyl methacrylate (HEMA) in the presence of copper phthalocyanine blue. The contact lens has an outer layer surrounded the core prepared by using the same core material except that there is no copper phthalocyanine blue. The contact lens has a water content of 35.7% (Example 1). Foley is silent on the DK of the contact lens.

However, Muller teaches that a typical HEMA contact lens with 39% of water content has an

oxygen permeability of 12×10^{-10} (cm)(cm³ O₂)/(sec.cm².cmHg). Therefore, Foley's contact lens has an oxygen permeability of about 12×10^{-10} (cm)(cm³ O₂)/(sec.cm².cmHg) (i.e., 12×10^{-11} (cm²)(ml O₂)/(sec.ml.mmHg)). Since Foley's contact lens is used in the eyes, the oxygen permeability of this contact lens must have a high enough oxygen permeability. Without specifying how high is the high oxygen permeability in the instant claim, Foley's contact lens reads on the limitation of the instant claim. Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when extra references are cited to A) Prove the primary reference contains an "enabled disclosure"; B) Explain the meaning of a term used in the primary reference; or C) Show that a characteristic not disclosed in the reference is inherent. See MPEP 2131.01. In this instance, Muller is cited here only for the purpose of showing Foley's contact lens has a DK which is about 12×10^{-10} (cm)(cm³ O₂)/(sec.cm².cmHg).

With respect to Claim 2, the outer layer is a hydrogel derived from a hydrophilic monomer (i.e., HEMA), which is contacted with eyes. In other words, the surface of the Foley's contact lens is in contact with an ophthalmic environment. Therefore, it is ophthalmically compatible.

With respect to Claim 3, the contact lens is for eye color modification (col. 2, lines 33-53).

With respect to Claim 5, the contact lens derived from a polymer matrix comprising a hydrophilic monomer of HEMA (Example 1).

With respect to Claim 6-8, as mentioned previously, copper phthalocyanine blue is used.

With respect to Claim 24, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i). As such, although Foley does not use a pigment dispersion which is prepared as a separate component from the “crosslinkable or polymerizable material”, Foley’s contact lens reads on the soft, tinted ophthalmic lens of the instant claim because the dispersing agent which is crosslinkable or polymerizable with component (i) in the instant claim is eventually incorporated into the final lens matrix (i.e., absence of the pigment dispersion) after polymerization or crosslinking.

With respect to Claim 25, the rejection for Claim 24 applies.

With respect to Claim 27, the copper phthalocyanine blue is dispersed in a monomer mixture comprising HEMA (Example 1).

With respect to Claims 29-30, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i) (i.e., using component (i) as the dispersing agent). As such, although Foley does not use a pigment dispersion which is prepared as a separate component from the “crosslinkable or polymerizable material”, Foley’s composition reads on the composition of the instant claim because the “pigment dispersion” is essentially the final “composition” in the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grolier (The Encyclopedia AMERICANA International Edition, Grolier Incorp., vol. 7, 1998, pages 685-686) in view of Molock (US 5,292,350).

Grolier discloses a contact lens, a small device that fits between the eye and the eyelids and can be worn instead of glasses for correction of defective vision (page 685, second paragraph).

The difference between Grolier and the present invention is the requirement of a soft, tinted contact lens.

Molock discloses a soft, hydrogel contact lens as described in paragraph 5, which is incorporated herein by reference. Molock's contact lens is intended to be used in the eyes (col. 4, lines 8-14). The motivation of using Molock's contact lens is to enables a wearer to visibly notice the lens during handling if temporarily misplaced (col. 4, lines 8-12). In light of the aforementioned benefit, it would have been obvious to one of ordinary skill in the art at the time of invention to use Molock's contact lens as Grolier's contact lens for vision correction.

9. Claim 23 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molock.

As mentioned previously, Molock discloses a soft, tinted ophthalmic molding obtained by polymerizing a polymer precursor having a dye dispersed therein. It is noted that Molock's process is not the same as Applicants' process because there is no use of a pigment (i.e., dye) dispersion that is prepared in a separate step. In other words, Molock's dye is dispersed in the

whole monomer mixture (corresponding the polymer precursor in step a) of Claim 9 of the instant invention), and the Molock's dispersing agent is indeed the whole monomer mixture. However, Claim 23 is a product-by-process claim. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.

As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

10. Claim 23 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Foley.

As mentioned previously, Foley discloses a soft, tinted ophthalmic molding obtained by polymerizing a polymer precursor having a dye dispersed therein (Example 1). It is noted that Foley's process is not the same as Applicants' process because there is no use of a pigment (i.e., dye) dispersion that is prepared in a separate step. In other words, Foley's dye is dispersed in the whole monomer mixture (corresponding the polymer precursor in step a) of Claim 9 of the instant invention), and the Foley's dispersing agent is indeed the whole monomer mixture. However, Claim 23 is a product-by-process claim. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or

similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

121. Claims 26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

None of Molock and Foley discloses the use of a siloxane-containing macromer having a diallyl siloxane group.

Allowable Subject Matter

12. Claims 9-22 are allowed.

13. The following is an examiner's statement of reasons for allowance:

None of Molock and Foley discloses a method for making a soft, tinted ophthalmic molding comprising a separate step of providing a pigment dispersion as set forth in the instant claims.

14. The following references cited in the specification have been considered: US 3,228,741 US 3,341,390; US 3,996,187; US 3,996,189; US 5,760,100; US 4,136,250; US 4,153,641; US 4,605,712; US 4,711,943; US 5,158,717; US 5,260,000; US 5,346,946; US 4,312,575; US 4,632,844; US 3,408,429; and US 4,347,198.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Kuo-Liang Peng

February 10, 2003

A handwritten signature in black ink, appearing to read "Kuo-Liang Peng".